

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
Express mail label number EL855044762US

Date of deposit May 7, 2001

I hereby certify that this paper or fee is being
deposited with the United States Postal Service
Express Mail Post Office To Addressee service
under 37 CFR 1.10 on the date indicated above
and is addressed to the Assistant Commissioner
for Patents, Washington D.C. 20231

Christine Wheeler

(Name of person mailing paper or fee)
Christine Wheeler
(Signature of person mailing paper or fee)

APPLICATION

Of

ROBERT B. CITRON

LAWRENCE L. HAMPTON

OLIVER D. BUCHERT

AND

HEATHER M. SAVAGE

For

UNITED STATES LETTERS PATENT

On

SURGICAL TRIMMING TOOL

Docket No. PSMED-39755

Sheets of Drawings: Six

Attorneys

KELLY BAUERSFELD LOWRY & KELLEY, LLP

6320 Canoga Avenue, Suite 1650

Woodland Hills, California 91367

SURGICAL TRIMMING TOOL

BACKGROUND OF THE INVENTION

The present invention generally relates to skull flap fastening systems. More particularly, the present invention relates to a surgical tool which facilitates the trimming of a cranial-flap clamp used in such fastening systems.

When brain surgery is performed, it is often necessary to remove a piece of the skull to provide access to the brain. This surgical procedure is often referred to as a craniotomy. A portion of the cranial vault is removed or folded back in a flap to permit surgical access to the cranial contents, such as the brain. This is often done with a hand-held, gas-powered surgical tool similar to a small router. After a small hole is made in which the bit of the router is placed, the bit is then guided to cut out the piece of the skull required. The blade cuts a small gap so that the piece removed does not fit back into its hole exactly.

After the brain operation, the skull flap must be replaced and held in position until the skull heals. Previously, a series of matching small holes were drilled in the edge of the skull and the edge of the skull flap. Sutures were then passed through the corresponding holes and the flap secured back into the skull opening from which it was taken. However, due to the inexact fit caused by the router bit, the flap sat slightly below the surface of the skull, resulting in a depressed area visible through the skin.

Stainless steel wire was substituted for the suture material, which is stronger than the suture material, but more cumbersome. The wire was prone to failure, particularly if over-twisted, and was found to be palpated through a skin scalp if not properly buried. Also, the introduction of computed tomography (CT), demonstrated extensive metal artifacts caused by these wires. Further, the common problem of skull flap settling remained.

More recently, cranial mini-plate fixation systems were developed. While these systems have been successful, they are time consuming and very expensive.

Even more recently, alternative cranial fixation systems comprised of cranial-flap clamps having opposing closure members, often disks, in which one disk is fixed to an end of a stem, while the other is movable along the stem towards the opposing closure member to clamp the skull and bone flap together. This method is faster than any of the other methods and less expensive and time consuming than the mini-plate fixation systems.

Tools have been devised for gripping the pin or stem of the clamp, and then pressing together the disks into a clamping formation. However, the process often takes more than one tool to complete, thus requiring both hands of the surgeon. Some of the tools require calibration before use. Another disadvantage of such tools is that they require special cleaning processes due to their complicated design. Some surgeons have also found these tools somewhat complicated in use and not intuitive.

The stem of the clamp must be removed once the plates are pressed together. Without a proper tool, great care must be taken that the trimmed portions of the stem not be left in the healing wound. Traditional trimming tools, such as wire cutters, can adequately cut the pin or stem from the clamp, but result in the cut portion being projected from the clamp. This cut portion could easily project itself into an area of the wound in which it is difficult to find and extract.

Accordingly, there is a need for a surgical trimming tool which is intuitive and easy to use. The trimming tool should retain the cut stem in place until it is intentionally removed from the tool. The tool should not require special cleaning processes, nor disassembly before its next use. The present invention fulfills these needs and provides other related advantages.

SUMMARY OF THE INVENTION

The present invention resides in a surgical trimming tool that can be used to trim and cut away a stem from a fastened cranial-flap clamp. The tool generally comprises first and second handles which are pivotally attached to one another intermediate first and second ends thereof. A first cutting jaw extends from the first end of the first handle, and a second cutting

jaw extends from the first end of the second handle. The first and second cutting jaws are configured to cooperatively cut an object when closed towards one another. A clip is associated with either the first or second cutting jaw, and is configured to retain the cut object between the clip and the closed jaws until the first and second jaws are separated, or until the cut object is forcibly removed from the clip.

The clip is generally S-shaped, with a first end attached to the associated first or second jaw, and a second end extending over a cutting edge of the associated first or second jaw. The clip is resiliently flexible and configured to flex upward as an object is cut, so as to retain the object between the second end of the clip and the associated first or second jaw. The second end of the clip preferably includes a sharp edge generally positioned over the cutting edge of the associated first or second jaw to aid in the retention of the cut object.

A spring is interposed between the first and second handles for biasing the first and second jaws into an open position. The spring preferably comprises first and second leaf springs. A first end of the first leaf spring is attached to the second end of the first handle, and a first end of the second leaf spring is attached to the second end of the second handle. The second ends of the first and second leaf springs are connected to each other so as to bias the jaws into an open position.

Use of the tool is advantageous in craniotomy procedures as the tool retains the cut stem within its closed jaws, or between the clip and a jaw, preventing the cut stem from projecting into the open area where it can be lost in bodily fluids or the like. The tool is also advantageous in that it does not require any specialized cleaning procedures. Although the tool is particularly adapted for use with such clamps used in refixing a bone flap to a cranium during a craniotomy, it is contemplated that it could be advantageously used in other procedures as well.

Other features and advantages of the present invention will become apparent from the following more detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of a tensioning tool embodying the present invention, illustrating the tensioning of cranial-flap clamps onto a bone flap and cranium, illustrated in phantom;

FIGURE 2 is a perspective of the tensioning tool of FIG. 1 actuating a cranial-flap clamp in phantom;

FIGURE 3 is a top plan view of the tensioning tool of the present invention;

FIGURE 4 is a top plan view of the tensioning tool of FIG. 3 in an opened state;

FIGURE 5 is a side elevational view taken generally along 5-5 of FIG. 3;

FIGURE 6 is a side elevational view taken generally along line 6-6 of FIG. 3;

FIGURE 7 is a cross-sectional view taken generally along line 7-7 of FIG. 3, and illustrating a ratcheting mechanism;

FIGURE 8 is a cross-sectional view taken generally along line 8-8 of FIG. 4;

FIGURE 9 is a perspective view of a trimming tool embodying the present invention removing a stem from a cranial-flap clamp tensioned onto a bone flap and cranium;

FIGURE 10 is a perspective view of the trimming tool of FIG. 9, illustrating the retention of the cut stem within jaws of the trimming tool;

FIGURE 11 is a top planar view of the trimming tool of the present invention in an opened state;

FIGURE 12 is a top plan view of the trimming tool of the present invention in a closed state;

FIGURE 13 is a side elevational view taken generally along line 13-13 of FIG. 12;

FIGURE 14 is a side elevational view taken generally along line 14-14 of FIG. 12;

FIGURE 15 is a fragmented perspective view of jaws of the trimming tool of the present invention being placed around a stem in phantom of a cranial-flap clamp;

FIGURE 16 is a fragmented perspective view of the trimming tool jaws of FIG. 15 closed upon the stem to cut the stem and retain the stem in the jaws of the trimming tool;

FIGURE 17 is a cross-sectional view taken generally along line 17-17 of FIG. 16; and

FIGURE 18 is a cross-sectional view taken generally along line 18-18 of FIG. 16, illustrating the retention of the stem within the jaws by virtue of a flexible clip associated with the jaws.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the present invention is concerned with a tensioning tool, generally referred to in the Figures by the reference number 10, and a trimming tool, generally referred to in the Figures by the reference number 12, which are particularly adapted for use in the replacement and fixation of a bone flap 14 after a craniotomy procedure.

With reference to FIG. 1, a craniotomy procedure involves creating a burr hole 16 into the skull or cranium 18 of a patient and subsequently using a high-speed craniotomy, or other dissecting or cutting tool to create a typically circular bone flap 14. The bone flap 14 is then removed, or pulled back in order that the surgeon can access the contents of the cranium 18 and perform the necessary procedures. After these procedures are performed, the bone flap 14 is replaced and fixed into position.

The tools 10 and 12 of the present invention are particularly adapted for use with cranial-flap clamps 20 used in locking the cranial bone flap 14 to the cranium 18. Such cranial-flap clamps have opposing closure members 22, such as the illustrated disks, positioned relative to each other on a stem 24, so that as a top closure member 22 is forced downwardly along the length of the stem 24, objects positioned between the two closure

members 22 are clamped to one another. Often, such closure members 22 are slightly parabolic and disk shaped, and may even include projections, to enhance the clamping and fixing effect. The stem 24 typically includes ridges or teeth along the length thereof which serve to hold the top closure member 22 in place, while permitting the top closure member 22 to be moved downward given the appropriate force while preventing upward travel of the top closure member. Such stems 24 often include a pressure release mechanism so that a portion of the stem 24 is automatically removed from the clamp 20 once the appropriate tension is achieved. Although such clamps 20 are made of a variety of materials, it is preferable that the clamps 20 be comprised of non-ferromagnetic polymer materials so that the clamps 20 will not interfere with CT or MR imaging. Although the invention is not limited to such, the tools 10 and 12 are particularly adapted for use with the clamps described in U.S. Patent No. 6,022,351 to Bremer et al., the contents of which are hereby incorporated by reference.

With reference now to FIGS. 3-6, the tensioning tool 10 of the present invention is comprised of a first handle 26 and a second handle 28 attached to one another at pivot point 30 intermediate first and second ends thereof. A first jaw 32 extends from the first end of the first handle 26. The first jaw 32 includes an aperture 34 which is configured to accept the stem 24 therethrough. A second jaw 36 extends from the first end of the second handle 28 and also has an aperture 38 which aligns with the first jaw aperture 34 when the jaws 32 and 36 are brought towards one another, and is configured to accept the stem 24 therethrough. Typically, the first and second jaw apertures 34 and 38 comprise open-faced channels to permit the surgeon to place the tool 10 directly onto the stem 24 of the clamp 20, or approach and insert the stem 24 into the apertures 34 and 38 from the side. While the illustrated configuration provides convenience to the surgeon, it is to be understood that it is merely important that the apertures 34 and 38 align with one another and accept the stem 24 therethrough.

A spring 40, or other appropriate biasing means, is positioned between the first and second handles 26 and 28 for biasing the first and second jaws 32 and 36 into contact with one another. In the particularly

preferred illustrated embodiment, the spring 40 comprises a first leaf spring 42 having a first end 44 attached to the second end of the first handle 26, and a second leaf spring 46 having a first end thereof 48 attached to the second end of the second handle 28, with the second ends 50 and 52 of the leaf springs 42 and 46 operably connected to one another. Typically, the second ends 50 and 52 are interlocked with one another by forming an aperture or notch in one end, with the other end having reduced diameter and fitting within the aperture so that flexation can occur without the first and second leaf springs 42 and 46 disconnecting from one another. The first ends 44 and 48 of the leaf springs 42 and 46 can be attached to the second end of the handles 26 and 28 by any appropriate means, including welding, riveting, or the like. The strength of the leaf springs 42 and 46 should be such that the first and second jaws 32 and 36 are biased towards one another, while allowing a surgeon to separate the jaws 32 and 36 by compressing the handles 26 and 28 with his or her hand 54 without excessive effort. As illustrated in FIGS. 5 and 6, the handles 26 and 28 may include raised bumps 56, or other surface irregularities, to enhance the grip of the surgeon.

Referring now to FIGS. 7 and 8, a cavity 58 is formed in the second jaw 36 which houses a ratcheting mechanism, generally referred to by the reference number 60. The cavity 58 is at least partly contiguous with the second jaw aperture 38 so that the ratcheting mechanism 60 can selectively lock the stem 24 in place within the second jaw aperture 38. In the illustrated preferred embodiment, the cavity 58 and second jaw aperture 38 are completely contiguous with one another to form a single cavity. The ratcheting mechanism 60 comprises a pawl attached to the second jaw 36 about pivot point 64, such as by a bolt or similar member extending across the cavity 58 of the second jaw 36. The pawl includes teeth 66 on an outer and upper edge thereof which are configured to press against and lock the stem 24 in place within the second jaw aperture 38 by pressing the stem 24 against a wall 68 of the second jaw 36.

A spring 70 biases the pawl teeth 66 against the second jaw wall 68, resulting in a portion of the pawl 72 to lie without the second jaw 36. The

spring 70 is typically wrapped around the pivot point 64, so that an end thereof rests on a lower second jaw wall 74, with the opposite end being attached to the pawl 62 itself.

As illustrated in FIG. 7, when the first jaw 32 is brought into contact with the second jaw 36, the first jaw 32 pushes against the extended portion 72 of the pawl 62 to pivot the pawl 62, resulting in the teeth 66 being removed from the upper second jaw wall 68. In this state, the stem 24 can be inserted through the aligned first and second jaw apertures 34 and 38. However, when the first jaw 32 is moved away from the second jaw 36, by pressing the first and second handles 26 and 28 towards one another, the ratchet spring 70 biases the pawl teeth 66 upward into contact with the second jaw upper wall 68, or stem 24 within the second jaw aperture 38 to hold the stem 24 in place. The pawl teeth 66 can be configured to engage the ratchet teeth or ridges (not shown) of the stem 24 to enhance this locking effect.

With reference again to FIGS. 1 and 2, after the craniotomy is performed, the cranial bone flap 14 is repositioned, and the clamps 20 inserted between the cranium 18 and bone flap 14 so that the lower closure member 22 rests beneath the cranium 18, while the upper closure member 22 is spaced above the cranium 18 and bone flap 14. Preferably, these clamps 20 are spaced equidistant from one another so that an equal amount of force is applied to the outer circumference of the bone flap 14. Sutures, such as tack-up sutures (now shown), may be applied between the clamps 20 for added support. With the clamp 20 in place, the stem 24 is inserted into the first and second jaw apertures 34 and 38. The tool 10 is positioned such that the first jaw 32 rests upon the top closure member 22. The handles 26 and 28 are then compressed by the surgeon's hand 54, resulting in the first and second jaws 32 and 36 being removed from one another, the pawl 62 pivoting such that the teeth 66 thereof lock the stem 24 in place within the second jaw aperture 38, while the first jaw 32 moves the upper closure member 22 downward. Preferably, the clamps 20 are all tensioned so that the upper closure member 22 contacts the cranium 18 and bone flap 14. At this point, tensioning is continued on each clamp 20 until a predetermined

amount of tension is achieved, or the safety tab portion of the stem 24 automatically breaks off indicating that the appropriate tension has been achieved.

With reference to FIGS. 9 and 10, after the clamp 20 has been properly tensioned onto the bone flap 14 and cranium 18, the stem 24, or the remainder thereof, is removed. Although this can be accomplished using a variety of trimming and cutting tools, the present invention provides a particularly useful trimming tool 12 which retains the cut portion of the stem 24 within the tool 12, as illustrated in FIG. 10, so that it is not accidentally left within the open wound area.

With reference now to FIGS. 11-14, the trimming tool 12 generally comprises first and second handles 76 and 78 pivotally attached to one another intermediate the first and second ends thereof. A first cutting jaw 80 extends from the first end of the first handle, and a second cutting jaw 82 extends from the first end of the second handle. The first and second cutting jaws 80 and 82 are configured to cooperatively cut an object, such as the stem 24 when closed towards one another. Such a handle and cutting jaw arrangement is well known in the art.

A spring, generally referring to by the reference number 84 is interposed between the first and second handles 76 and 78 for biasing the first and second jaws 80 and 82 into an open position, as illustrated in FIG. 11. In the illustrated preferred embodiment, the spring 84 comprises a first leaf spring 86 having a first end 88 attached to the second end of the first handle 76, and a second leaf spring 90 having a first end thereof 92 attached to the second end of the second handle 78, with the second ends 94 and 96 of the leaf springs 86 and 90 operably connected to one another. Typically, the second ends 94 and 96 are interlocked with one another by forming an aperture or notch in one end, and with the other end being of reduced diameter and fitting within the aperture so that flexion can occur, without the first and second leaf springs 86 and 90 disconnecting from one another. The first ends 88 and 92 of the leaf springs 86 and 90 can be attached to the second end of the handles 76 and 78 by any appropriate means, including welding, riveting, or the like. The strength of the leaf springs 86 and 90

should be such that the first and second jaws 80 and 82 are biased towards one another, while allowing a surgeon to separate the jaws 80 and 82 by compressing the handles 76 and 78 with his or her hand 54 without excessive effort.

A clip 98 is associated with either the first or second cutting jaw 80 or 82 and is configured to retain the cut object, such as the illustrated stem 24, between the clip 98 and the closed jaws 80 and 82 until the jaws 80 and 82 and are separated from one another, or the object is forcible removed from the clip 98. The clip 98 is typically generally S-shaped, with a first end 100 attached to the associated first or second jaw 80 or 82. The first end 100 of the clip 98 can actually be fitted into a recess formed in the first or second jaw 80 and 82 or 82. The remainder of the clip 98 extends over the jaw 80 or 82 in stepped fashion so that the second end 102 of the clip 98 rests above a cutting edge 104 of the jaw 80 or 82, as illustrated in FIGS. 13 and 14.

With reference now to FIGS. 15-18, the second clip end 102 is actually bent so that it lies transverse to the longitudinal axis of the remainder of the clip 98 and is positioned directly over the cutting edge 104 of the jaw 80 or 82. Preferably, the second end 102 includes a sharpened edge 106, as will be described more fully herein.

The stem 24 is placed between the open jaws 80 and 82, as illustrated in FIG. 15. The handles 76 and 78 are then compressed causing the jaws 80 and 82 to come into contact with one another and cut the stem 24, as illustrated in FIG. 16. With particular reference to FIGS. 17 and 18, the clip 98 is in a downward and resting position when the jaws 80 and 82 are separated from one another. However, upon closing the jaws 80 and 82 together, the cutting edges 104 of the jaws 80 and 82 serve to cut the stem 24, while the second end 102 of the clip 98 is flexed upward by contact with the stem 24. With the jaws 80 and 82 in closed position, the stem 24 is compressibly retained between the clip 98 and jaws 80 and 82. Thus, the surgeon can keep the jaws 80 and 82 in closed position with the stem 24 retained therein to safely remove the stem 24 for disposal. The sharpened edge 106 of the clip 98 facilitates this retention by cutting into a portion of the

stem 24 to more securely hold the stem 24 in place. The sharpened edge 106 may in some instances actually retain the stem 24 even when the jaws 80 and 82 are opened from one another. In this case, the stem 24 is removed by grasping the stem 24 and pulling it away from the clip 98.

The trimming tool 12 is designed such that the stem 24 is removed nearly flush with the top closure member 22. This prevents unsightly bumps, or undue irritation, when the scalp is placed over the cranium 18 after the procedure.

Although the trimming tool 12 has been illustrated and described with respect to a craniotomy procedure, it is to be understood that the retention aspect of this tool 12 could conceivably be taken advantage of in other applications.

The tools 10 and 12 of the present invention are advantageous to prior existing tools in that they are intuitive and easy to use with a single hand. This frees the other hand of the surgeon to do other things, such as holding or positioning the clamp 20. The tools 10 and 12 are fairly simple in construction, making them inexpensive in comparison to other devices. No calibration nor assembly is required before their use. The tools 10 and 12 are capable of being reused and sterilized with conventional methods, such as autoclave, without disassembly. Although the tools 10 and 12 are preferably comprised of a durable and sterilizable material, such as steel, they can also be disposable and comprised of plastic or the like.

Although several embodiments have been described in detail for purposes of illustration, various modifications of each may be made without departing from the scope and spirit of the invention. Accordingly, the invention is not to be limited, except as by the appended claims.